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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,465	07/26/2001	Gordon A. Andrews	55280	8758

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EXAMINER
GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,465	ANDREWS ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-18 and 22, with traverse, in Paper No. 4, filed 10/9/02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election, without traverse (MPEP § 818.03(a)). Claims 19-21 have been cancelled by Applicant without prejudice. Accordingly, claims 1-18 and 22 are pending and are under examination.

Specification

2. The use of the trademark PathoDx and Stabilicoat in page 7 of the specification has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting, "a substrate member for facilitating contact between at least one monoclonal antibody and a feline blood sample" because it is unclear how the "member" in question is part of the "substrate". Further, it is unclear what Applicant intends to encompass in using the term, "facilitating" as recited in the claim.

Claim 2 lacks clear antecedent support in reciting, "wherein one monoclonal antibody ... recognizes glycolipid A antigen $(NeuGc)_2G_{D3}$" because claim 1 from which it depends recites a "first" monoclonal antibody and a "second" monoclonal antibody in part b).

Claim 3 lacks clear antecedent support in reciting, "wherein one monoclonal antibody ... recognizes glycolipid A antigen comprising $(NeuGc)G_{T3}$ or (NeuGc)" because claim 1 from which it depends recites a "first" monoclonal antibody and a "second" monoclonal antibody in part b).

Claim 9 is vague and indefinite in reciting, "a substrate member ... consisting of card members" because it is unclear how the "members" in question are part of the "card".

Claim 12, step b) is vague and indefinite because it is unclear what structural and functional cooperative relationship exists between the recited "substrate member" and the "first monoclonal antibody" and the "second monoclonal antibody". Specifically,

claim 12 recites that after collection of the blood sample from the feline subject, an amount of the blood sample is dispensed into the "substrate member" wherein it is contacted to a first monoclonal antibody and a second monoclonal antibody. However, claim 12 fails to distinctly recite that the first and the second monoclonal antibody mixture is 1) immobilized on the substrate or otherwise, 2) previously or subsequently added to the blood sample. Please clarify.

Claim 12 is vague and indefinite in reciting, "each said antibody recognizing feline blood group A specific antigens" because it is unclear what Applicant intends to encompass in reciting the term "recognizing" as used in the claim. Does Applicant intend that the antibodies "specifically bind" the feline blood group A specific antigens present in the sample.

Claim 12, step c) is ambiguous in relation to the preamble because it does not specifically define how "sample agglutination" relates to "feline blood typing" as required by the preamble.

Claim 12 is vague and indefinite in reciting, "a substrate member which facilitates contact between a mixture of a monoclonal antibody and a second monoclonal antibody" because it is unclear how the "member" in question is part of the "substrate". See also claim 13. Further, it is unclear what Applicant intends to encompass in using the term, "facilitates" as recited in the claim.

Claim 13 is indefinite in reciting "EDTA". Acronyms or abbreviations must be recited at least one time in a set of claims.

Claim 13 lacks antecedent support in reciting, "each cat to be typed" because claim 12 from which depends recites "a feline subject".

Claim 14 lacks clear antecedent support in reciting, "wherein one monoclonal antibody ... recognizes glycolipid A antigen $(NeuGc)_2G_{D3}$" because claim 12 from which it depends recites a "first" monoclonal antibody and a "second" monoclonal antibody in step b).

Claim 15 lacks antecedent support in reciting, "said 13G3 antibody". Additionally, it is unclear how the "13G3 antibody" relates to the first monoclonal antibody and/or the second monoclonal antibody recited in claim 12 from which it depends.

Claim 16 lacks antecedent support in reciting, "said 4E10 antibody". Additionally, it is unclear how the "4E10 antibody" relates to the first monoclonal antibody and/or the second monoclonal antibody recited in claim 12 from which it depends.

Claim 17 is vague and indefinite in using the term, "sufficient" because the term "sufficient" is a subjective term that lacks a comparative basis for defining its metes and bounds.

Claim 18 provides for the use of monoclonal antibodies to type feline blood, but, since the claim does not set forth steps involved in the method/process of typing feline blood, other than contacting the feline blood sample with the monoclonal antibodies, it is unclear what method/process applicant is intending to encompass. A claim is indefinite and incomplete, where it merely recites a use without complete active, positive steps delimiting how this use is actually practiced.

Claim 22 is vague and indefinite in reciting, "a substrate member for facilitating contact between a monoclonal antibody mixture ... and a feline blood sample" because it is unclear how the "member" in question is part of the "substrate". Further, it is unclear what Applicant intends to encompass in using the term, "facilitating" as recited in the claim.

Claim 22 is vague and indefinite in reciting, "two separate monoclonal antibodies" because it is unclear as to whether Applicant intends to encompass "separately contained monoclonal antibody mixtures" or "two distinct sets of monoclonal antibodies in a mixture".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 1-5, 9-14, and 17-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by 1) Green et al. (Comparative Haematology, 2000).

1) Green et al. teach determining feline blood type using monoclonal antibodies 13G3 and 4E10 that are added to feline blood sample on test cards or test tubes upon which the mixture is tested by direct agglutination reaction. MoAbs 13G3 and 4E10 are specific for $(NeuGc)_2G_{D3}$, the major glycolipid antigen of feline type A blood, and $(NeuGc)G_{T3}$ which is a slower migrating glycolipid band; 4E10 does not detect all blood type A samples but does not agglutinate when tested with type B feline blood samples (see Abstract, Materials (kits) and Methods: page 31, column 2, and page 33, columns 1-2). 1) Green et al. also teach that wheat germ lectin from Triticum vulgaris is used to detect feline type B blood (see page 31, column 1, second and third full paragraphs). 1) Green et al. specifically teach using 50 ul of whole blood sample to react with the antibodies in agglutination reactions on test typing cards (see page 31, column 2, third full paragraph).

5. Claims 1-5, 10-12, 14, and 17-18 are rejected under 35 U.S.C. 102(e2) as being clearly anticipated by 2) Green et al. (AVHTM meeting, 2001).

2) Green et al. teach determining feline blood type using monoclonal antibodies 13G3 and 4E10 that are added to feline blood sample and tested for reaction by direct agglutination reaction. MoAbs 13G3 and 4E10 both detect feline blood type A by reaction with $(NeuGc)_2G_{D3}$, the major glycolipid antigen of feline type A blood. Additionally, the mixture comprising both of 13G3 and 4E10 agglutinate all type AB feline blood samples. 2) Green et al. also teach that wheat germ lectin is used to detect feline type B blood. See entire Abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 6-8, 15-16, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Green et al. (Comparative Haematology, 2000).

1) Green et al. have been discussed supra. 1) Green et al. differs from the instant invention in failing to lyophilize the antibody mixture. However, 1) Green et al. at page 32, column 1, first full paragraph, teach extraction and lyophilization (dried) of lipids extracted from erythrocyte membranes using a stream of nitrogen.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have lyophilized the monoclonal antibody mixture of Green because

lyophilization of proteins and lipids is conventional or standard laboratory practice used in lengthening shelf life of standards and reagents.

1) Green et al. differs from the instant invention in failing to teach monoclonal antibody concentrations of 34 ug/ml and 136 ug/ml in claims 6, 15, and 22 and monoclonal antibody concentrations of 64 ug/ml and 256 ug/ml in claims 7, 8, and 22 for use in methods and kits therefor.

However, it is maintained that concentrations of reagents in mixtures, i.e. 100 ul of lectin (60 ug/ml dilution in PBS) or 100 ul sample of hybridoma media from each MoAb in 100 ul 1% saline suspension, are all result effective variables which Green et al. have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 6-7, 15-16 and 22 are for any particular purpose or solve any stated problem and the prior art teaches that reagent concentrations often vary according to the sample being analyzed, and various

combinations of parameters appear to work equally as well, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by Green et al. by normal optimization procedures.

7. No claims are allowed.

Remarks

8. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Andrews et al. (Blood, 79(9) : 2485-2491, (May 1991)) teach Triticum vulgaris and monoclonal antibodies 32-27 in feline blood typing tests using card agglutination tests (see page 2485, 2486 and 2488).

Griot-Wenk et al. (Animal Genetics 24: 401-407 (1993)) teach biochemical characterization of the feline AB blood group system.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday, 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 308-3399. The fax phone numbers for

the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
December 27, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/27/02